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10 *Attorneys for Defendants*
11 *C. R. Bard, Inc. and*
12 *Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

16 IN RE: Bard IVC Filters Products Liability
17 Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' SEPARATE
STATEMENT OF FACTS IN
SUPPORT OF MOTION FOR
SUMMARY JUDGMENT AS TO
PLAINTIFFS DORIS AND ALFRED
JONES'S CLAIMS**

21 DORIS JONES and ALFRED JONES, a
22 married couple,

(Assigned to the Honorable David G. Campbell)

23 || Plaintiffs,

24 | v.

25 C. R. BARD, INC., a New Jersey
26 corporation and BARD PERIPHERAL
VASCULAR, INC., an Arizona
corporation,

Defendants.

1 Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order
2 No. 53 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.
3 (collectively “Bard”) respectfully submit this Separate Statement of Facts in Support of
4 Motion for Summary Judgment as to Plaintiffs Doris and Alfred Jones’s Claims.

5 1. Plaintiff Doris Jones received a Bard Eclipse® Filter (the “Filter”) [REDACTED]
6 [REDACTED]
7 [REDACTED] (Ex. A, Plaintiff Fact Sheet of Plaintiff Doris Jones (hereinafter
8 “PFS”), at §§ II.2(a), II.3; Ex. B, Selected Plaintiff Medical Records, at
9 JONESD_MUMC_MDR01287-88).

10 2. The Filter is not sold directly to patients. (Ex. C, Eclipse Filter Instructions
11 for Use (the “Eclipse IFU”) at page 1.)

12 3. In 2006, before the Filter was implanted, Ms. Jones experienced [REDACTED]
13 [REDACTED]
14 [REDACTED] (Ex. B, Selected Plaintiff
15 Medical Records, at JONESD_UFHJ_MDR00266).

16 4. In 2009, Ms. Jones was [REDACTED]
17 [REDACTED] (*Id.* at JONESD_MUMC_MDR01548-1549).

18 5. Despite her doctors’ earlier advice, [REDACTED]
19 [REDACTED]
20 [REDACTED] (*Id.* at JONESD_MUMC_MDR00452-456).

21 6. She had also previously been told [REDACTED]
22 [REDACTED] (*Id.* at JONESD_MUMC_MDR00723).

23 7. In August 2010, Ms. Jones again [REDACTED]
24 [REDACTED]
25 [REDACTED] (*Id.* at
26 JONESD_MUMC_MDR01287-88).

27 8. Ms. Jones’ implanting physician, Dr. Anthony Avino, testified that [REDACTED]
28 [REDACTED]

1 [REDACTED]
 2 [REDACTED] (Ex. D,
 3 March 23, 2017, Deposition Transcript of Anthony Avino, M.D. ("Avino Dep. Tr.") at
 4 110:22 to 113:25.)

5 9. [REDACTED]
 6 [REDACTED] (Ex. B, Selected Plaintiff Medical Records, at
 7 JONESD_MUMC_MDR01287-88).

8 10. Dr. Avino testified that [REDACTED]
 9 [REDACTED]
 10 (*Id.* at ¶ #). [REDACTED] (Ex. D, Avino Dep. Tr. at 54:14 to
 11 55:8.)

12 11. [REDACTED] (Ex. B, Selected Plaintiff Medical
 13 Records, at JONESD_MUMC_MDR01287-88).

14 12. Dr. Avino testified that he does not recall ever reading the IFU. (Ex. D,
 15 Avino Dep. Tr. at 47:21-23)

16 13. Dr. Avino was "generally familiar with IVC filter IFUs, if they warn of
 17 things like fractures, migration, perforation, tilt; complications like that," and began
 18 implanting IVC filters during his residency, 20 years before he implanted Ms. Jones'
 19 filter. (*Id.* at 8:16-23; 29:15-25; 48:2-7.)

20 14. The Eclipse IFU applicable in August 2010 (when Plaintiff received her
 21 Filter) included the following warnings:

22 • Under the bolded heading "**Warnings**" the Eclipse® IFU reads as
 23 follows:

24 • Filter fractures are a known complication of vena cava filters. There
 25 have been some reports of serious pulmonary and cardiac complications
 26 with vena cava filters requiring the retrieval of the fragment utilizing
 endovascular and/or surgical techniques.

27 (Ex. C, Eclipse IFU at p. 2.)

28 //

15. This warning is repeated under the bolded heading “**Potential Complications**”, which also adds that:

* * *

All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

(*Id.* at pp. 2-3.)

16. The "Clinical Experience" section notes the number of fracture observed during the clinical study of one hundred patients. (*Id.* at p. 4.)

17. In April 2015, Ms. Jones

Plaintiff Medical Records, at JONESD_MUMC_MDR00007-00011.)

18.

(*Id.* at JONESD MUMC MDR00114-115.)

19.

(*Id.*; *Id.* at JONESD MUMC MDR00065.)

20

at JONESD MUMC MDR00004-6).

21. Plaintiff's expert, Dr. Muehrcke, acknowledges that all IVC filters are known to have potential complications, including filter fracture, migration, tilt, and perforation. (Ex. E, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript ("Muehrcke Dep. Tr."), at 55:22 to 57:9.)

22. The plaintiffs' engineering expert testified that he is not aware of any IVC filter that has been developed that is complication free, (Ex. F, July 19, 2016 Dr. Robert McMeeking Deposition Transcript, at 133:19 to 134:19), nor is he aware of any implantable medical device that is one hundred percent complication free. (Ex. G, April

1 22, 2014 Dr. Robert McMeeking Deposition Transcript, at 149:9-13).

2 23. As the plaintiffs' experts recognize, “[e]very filter can have a complication;”
 3 therefore, it would be “unrealistic” for a physician implanting a Bard IVC filter to expect
 4 that the filter would never migrate, tilt, perforate, or fracture. (Ex. E, Muehrcke Dep. Tr.
 5 at 102:16 to 103:2).

6 24. The Filter was cleared by the FDA for retrievable use on January 14, 2010,
 7 through the 510(k) process outlined in the Food, Drug, and Cosmetic Act. (Ex. H, August
 8 29, 2005 FDA Clearance Letter¹).

9 RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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 23 Bard Peripheral Vascular, Inc.**

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27 ¹ Available at https://www.accessdata.fda.gov/cdrh_docs/pdf9/K093659.pdf, last accessed
 28 August 25, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.